

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

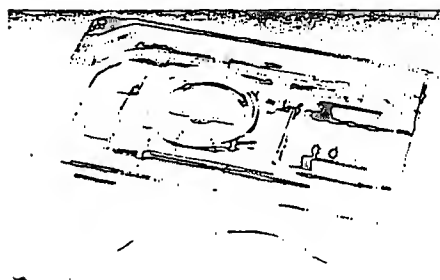
- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

PolyCath™

Shear-Resistant, Custom-Fitting Polyurethane Central Venous Catheter



Sterile Procedure Placement Tray

Features and Benefits Summary

- Provides high strength resistance to shearing
- Trimmable length for custom fit
- Dacron® cuff anchors catheter
- Extra-smooth surfaces guard against thrombosis
- Highly visible radiopaque polyurethane
- Thin wall construction combines high flow with a low outer diameter
- Two-part construction simplifies implantation and sizing
- Quick-connect bayonet lock attaches catheter and infusion set safely and securely
- Polyurethane softens at body temperature for patient comfort
- Easy-grip luer locks
- Replacement Kit and Injection Caps also available
- Supplied sterile in convenient tray with all necessary components for placement



Strato Medical Corporation
123 Brimbal Avenue
Beverly, MA 01915

Ordering Information

CVC 100-50
(Length 50cm)

PolyCath Polyurethane Central Venous Catheters and 9 French Introducer Kits.

CVC 100-65
(Length 65cm)

Contents: Polyurethane central venous catheter, I.D. 1.6 mm x O.D. 2.8 mm; silicone catheter extension assembly; 9 French peel-away sheath introducer and dilator; 10 ml syringes; 76 cm, 0.038 inch flexible stainless steel "J" guidewire with tip straightener; Dacron® cuff; disposable scalpel; CSR wrap; surgical drape; stainless steel tunneling trocar; 18 gauge, 2 3/4 inch extra thin wall needle; gauze pads, 4 inch x 4 inch; 22 gauge needles; foam swabs; injection cap; instructions for use.

CVC 101

PolyCath Replacement Catheter Extension with Injection Cap. For use with CVC 100-50 and 100-65 single lumen catheters.

Contents: Catheter extension assembly; catheter lock with suture tab; injection cap; instructions for use.

CVC 200-60
(Length 60cm)

PolyCath Polyurethane Dual Lumen Central Venous Catheters and 10 French Introducer Kits.

CVC 200-68
(Length 68cm)

Contents: Polyurethane central venous catheter, I.D. 1.4 mm equiv. x O.D. 3.0 mm; silicone catheter extension assembly; 10 French peel-away sheath introducer and dilator; 10 ml syringes; 76 cm, 0.038 inch flexible stainless steel "J" guidewire with tip straightener; Dacron® cuff; disposable scalpel; CSR wrap; surgical drape; stainless steel tunneling trocar; 18 gauge, 2 3/4 inch extra thin wall needle; gauze pads, 4 inch x 4 inch; 22 gauge needles; foam swabs; injection caps; instructions for use.

CVC 201

PolyCath Replacement Catheter Extension with Injection Caps. For use with CVC 200-60 and 200-68 dual lumen catheters.

Contents: Catheter extension "Y" assembly; catheter lock with suture tab; injection caps; instructions for use.

CVC 102

PolyCath Replacement Injection Caps. Individually packaged, sterile, and non-pyrogenic, ready for use. 50 units per case. Fit all PolyCath catheters.

Product specifications are subject to change.

For more information on the PolyCath™ Central Venous Catheter, please call **Toll Free (800) 637-5006** or contact your Strato Distributor. In Massachusetts call (508) 927-9419.

Distributed by:

*Aiken DA, Minton JP. The "pinch-off" sign: A warning of impending problems with permanent subclavian catheters. Am J Surg. 1984; 148:633.

PolyCath is a trademark of Strato Medical Corporation. Patents pending.
Strato is a registered trademark of Strato Medical Corporation.
Dacron is a registered trademark of E.I. DuPont de Nemours and Co., Inc.
Caution: Federal (U.S.A.) law requires that this device be used in strict accordance with Strato labeling noting indications, contraindications, warnings, precautions, and adverse effects of these devices. Federal (U.S.A.) law also restricts these devices to sale by or on the order of a physician.

Printed in U.S.A. © 1980, Strato Medical Corporation 1190

PolyCath™

Shear-Resistant, Custom-Fitting Polyurethane Central Venous Catheter

The PolyCath™ Central Venous Catheter provides an improvement in several critical areas of CV catheter placement and access—ease of implantation and sizing, stability, resistance to catheter shearing¹, and catheter diameter.

PolyCath: the high strength, high flow CV catheter.

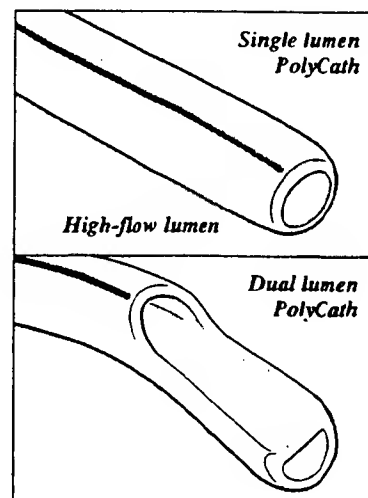
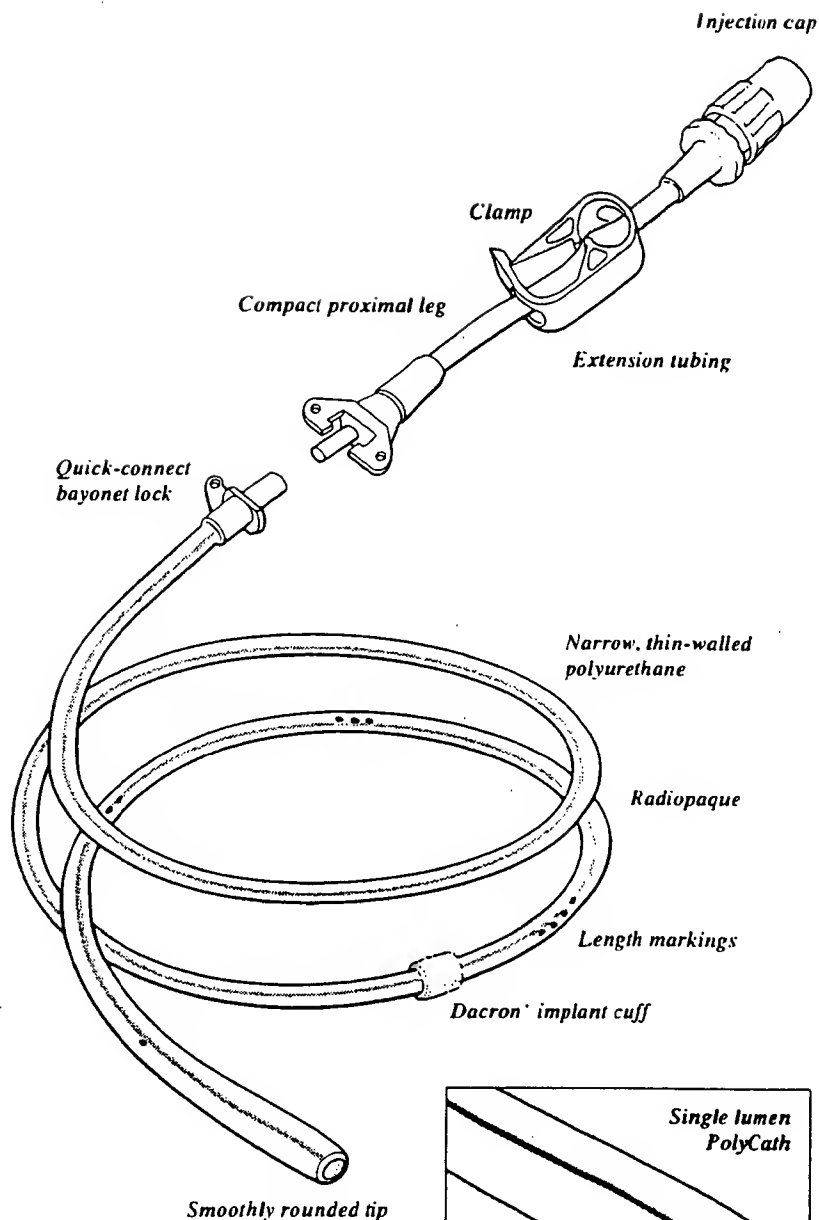
PolyCath is made of an exclusive, biocompatible polyurethane material with inherent advantages over others used for central venous access, notably silicone. Its high abrasion resistance helps prevent the problem of catheter shearing, while its smooth surface guards against thrombosis.

The added strength of the PolyCath material also allows for a thinner wall. As a result, the inner lumen has been enlarged for improved flow, without increasing the catheter's outer diameter. Similar performance is obtained using the PolyCath dual lumen CV catheter.

Simplified implantation and sizing.

The PolyCath catheter is first implanted and trimmed to the appropriate length (usually several inches outside the percutaneous exit site). It is then connected to the extension tubing—using Strato's exclusive quick-connect bayonet lock for a safe and secure attachment. A pre-attached Dacron[®] cuff promotes tissue ingrowth, adding stability and infection resistance.

Within minutes of implantation, moreover, the PolyCath material softens, and remains so for improved patient comfort. The radiopaque PolyCath is highly visible for easy verification of the catheter position at any future time.



Innovators in Vascular Access